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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,568	05/02/2002	Dan L. Eaton	P3230R1C48	9762
7590	10/15/2004			
MARK T. KRESNAK, Ph.D. GENENTECH INC. 1 DNA WAY MS49 SOUTH SAN FRANCISCO, CA 94080			EXAMINER HUNNICUTT, RACHEL KAPUST	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/063,568

Applicant(s)

EATON ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **RESPONSE TO AMENDMENT**

Applicant's amendment filed August 9, 2004 is acknowledged. Claim 6 has been canceled. Claims 1-5 are amended. Claims 1-5 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections/Objections Withdrawn***

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, regarding the term "stringent conditions" is withdrawn in response to Applicant's cancellation of this claim.

The rejection of claim 6 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,546 is withdrawn in response to Applicant's cancellation of the claim. The rejection of claim 6 under 35 U.S.C. 102(e) as being anticipated by Chen, Ople *et al.*, and Fox *et al.* is withdrawn in response to Applicant's cancellation of the claim.

The declaration filed on August 9, 2004 under 37 CFR 1.131 has been considered, however a declaration filed under 37 CFR 1.131 must be signed by all of the inventors of the subject matter of the rejected claims. The declaration filed on August 9, 2004 was only signed by William Wood. Thus, the declaration cannot be considered as evidence. However, the international patent application publication WO 99/63088 filed on June 2, 1999 (filed as Exhibit 1) is duly noted. The sequences of the current application were disclosed in U.S. provisional application 60/089653 filed on June 17, 1998. Therefore, the current application has a priority date of June 17, 1998. The priority date of June 17, 1998 is prior to the effective filing dates of

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U.S. Patent No. 6,468,546, Chen, Ople *et al.*, and Fox *et al.* As such, claims 1-5 are not anticipated by U.S. Patent No. 6,468,546, Chen, Ople *et al.*, or Fox *et al.* Therefore, the rejection of claims 1, 2, and 4-5 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,546 is withdrawn. The rejection of claims 1-5 under 35 U.S.C. 102(e) as being anticipated by Chen, Ople *et al.*, or Fox *et al.* is withdrawn.

Applicants state in their response that the provisional applications cited in the different publications were not available to Applicants. Applicants are referred to the public PAIR website (<http://portal.uspto.gov/external/portal/pair>), which has made IFW scanned documents available to the public since July 30, 2004. All of the cited provisional applications can be viewed on the PAIR website.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 31 and 35). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 101***

The rejection of claim 6 under 35 U.S.C. 101 is withdrawn in response to Applicant's cancellation of the claim. The rejection of claims 1-5 under 35 U.S.C. 101 is maintained for reasons of record on p. 3-4 of paper no. 0604.

Applicants argue that the claimed antibodies are useful as diagnostic probes for the determination of esophageal or lung tumor in human tissue samples of previously unknown morphology (p. 6 of response). Applicants refer to the data in Example 18 which demonstrates that the polynucleotide consisting of SEQ ID NO: 59 is "detectably overexpressed in human esophageal tumor as compared to its normal tissue counterpart...and is also detectably overexpressed in human lung tumor as compared to its normal tissue counterpart" (p. 6 of response).

Applicant's arguments have been fully considered but have not been found to be persuasive. Tissue-specific expression such as that found in Example 18 is not specific to the polynucleotide encoding the polypeptide of SEQ ID NO: 60. It does not depend on any characteristics of the nucleic acid molecule itself. Regarding Applicant's argument that the PRO polypeptide has a specific and substantial utility as being used as a diagnostic target for the determination of esophageal or lung tumor, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In Example 18, the specification merely states that the gene is "more highly expressed" in one tissue as compared to another. There is no guidance in the specification as to how high the levels are. There is no information in the specification as to the types of tumors, malignant or benign, that are affected. Applicants do not provide any evidence that indicates what the differences were or whether the results were statistically significant. Applicants have provided no indication of the nature of number of samples that were used. The art teaches that individual changes may be associated with clonal expansion, which would not be characteristic of the class of tumors as a whole (see, for example, Bover *et al.* 1998, *Cell. Mol. Biol.* 44(3): 493-504). The only thing Applicants teach is that the gene was "more highly expressed", and this does not enable the skilled artisan to differentiate amongst expression levels in order to diagnose any diseases.

Because the polypeptides comprising SEQ ID NO: 60 do not have a utility as a diagnostic marker for esophageal or lung tumors, the claimed antibodies which bind to polypeptides comprising SEQ ID NO: 60 also have no utility. The claimed antibodies would not be useful as diagnostic probes because polypeptides comprising SEQ ID NO: 60 are not useful as diagnostic markers. The claimed antibodies would not be diagnostically useful because the skilled artisan would not know how to use them to diagnose anything.

***Claim Rejections - 35 USC § 112***

The rejection of claim 6 under 35 U.S.C. 112, first paragraph, for lack of enablement due to the invention not being supported by a specific or substantial asserted utility or a well-established utility, is withdrawn in response to the cancellation of the claim. The rejection of claims 1-5 is maintained for reasons of record on p. 5 of paper no. 0604.

***Conclusion***

NO CLAIMS ARE ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH

10/13/04

  
JANET ANDRES  
PRIMARY EXAMINER